IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

SHIRLEY GROSS
1874 ADDISON ROAD SOUTH
DISTRICT HEIGHTS, MARYLAND 20747

Plaintiff,

VS.

PFIZER, INC.
1635 MARKET STREET
PHILADELPHIA, PA 19103

SERVE:
CT Corporation System,
1635 Market Street,
Philadelphia, PA 19103.

And

WYETH, INC.
5 GIRALDA FARMS
MADISON, NJ 07940

SERVE:
CT Corporation System,
1635 Market Street,
Philadelphia, PA 19103.

And

WYETH PHARMACEUTICALS, INC.
500 ARCOLA ROAD
COLLEGEVILLE, PA 19426

SERVE:
CT Corporation System,
1635 Market Street,
Philadelphia, PA 19103.

And

SCHWARZ PHARMA, INC.
103 FOULK ROAD
WILMINGTON, DE 19803

CASE NO. _____

PLAINTIFF'S COMPLAINT AND JURY DEMAND

SERVE:
CSC Entity Services, LLC
2711 Centerville Road,
Wilmington, Delaware 19808
And

PLIVA USA, INC.
425 PRIVET ROAD
HORSHAM, PA 19044

SERVE:
650 Cahill Road, Sellersville
Pennsylvania 18960
AND
1090 Horsham Road
North Wales, Pennsylvania 19454.

And

TEVA PHARMACEUTICALS USA, INC.
1090 HORSHAM ROAD
NORTH WALES, PA 19454

SERVE:
650 Cahill Road, Sellersville
Pennsylvania 18960
AND
1090 Horsham Road
North Wales, Pennsylvania 19454.

Defendants.

PLAINTIFF'S COMPLAINT AND JURY DEMAND

NOW COMES the Plaintiff, Shirley Gross, by and through her attorneys, and for her causes of action, sues the defendants, and alleges as follows:

PARTIES

1. Plaintiff, Shirley Gross (hereinafter sometimes referred to as "Ms. Gross" or Plaintiff), is an individual who is a resident and citizen of District Heights, Prince Georges County, Maryland.

2. Plaintiff brings this action and in her own right for purposes of recovering all damages

allowable by law for injuries suffered as a result having ingested Reglan/metoclopramide HCL ("Reglan/metoclopramide").

3. Defendant Pfizer, Inc. (hereinafter referred to as "Pfizer") is a Delaware corporation with its principal place of business in New York. Defendant Pfizer, Inc. has merged and/or acquired Co-Defendant Wyeth. Reference to Pfizer includes Pfizer individually, and collectively all divisions and/or subsidiaries, as well as successor-in-interest to Wyeth, A.H. Robins, Inc., American Home Product Corporation and ESI, Lederle, Inc. Pfizer may be served at its principal place of business located at 235 East 42nd Street, New York, NY 10015 and through their registered agent: CT Corporation System, 1635 Market Street, Philadelphia, PA 19103.

4. Defendant, Wyeth, Inc., d/b/a Wyeth is a Delaware corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940 and regularly conducts business in the State of Maryland.

5. Defendant, Wyeth Pharmaceuticals, Inc., has a principal place of business at 500 Arcola Road, Collegeville, Maryland 19426 and regularly conducts business in Maryland. References in this Complaint to Defendant "Wyeth", shall include collectively Defendants, Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. and shall also include individually and collectively all current and/or former divisions and/or subsidiaries, Wyeth as successor in interest to A.H. Robins, Inc., American Home Product Corporation, and ESI, Lederle, Inc. Based upon information and belief, Wyeth manufactures and distributes generic Reglan/metoclopramide through its ownership of ESI Lederle, Inc., ("ESI") a former subsidiary which merged into Wyeth and regularly conducts such business in Maryland, for which it derives significant and regular income.

6. Defendant, Schwarz Pharma, Inc., ("Schwarz") a manufacturer and distributor of Reglan/metoclopramide, is a Delaware corporation, with its principal place of business in Mequon,

Wisconsin, duly qualified to do business in the State of Maryland and may be served with process through its registered agent: CSC Entity Services, LLC, 2711 Centerville Road, Wilmington, Delaware 19808. References to Schwarz include Schwarz individually and collectively all of its predecessors in interest and divisions. Schwarz regularly conducts significant business in the State of Maryland.

7. Defendant Pliva USA, Inc., (hereinafter referred to as "Pliva") is a New York corporation with its principal place of business in New Jersey. Pliva is a wholly owned subsidiary of Barr Pharmaceuticals, Inc., which has recently been acquired by Teva. Pliva may be served with process at 650 Cahill Road, Sellersville, Maryland 18960 and 1090 Horsham Road, North Wales, Maryland 19454.

8. Defendant, Teva Pharmaceuticals USA, Inc., (“Teva”) a manufacturer and distributor of generic Reglan/metoclopramide is a Delaware corporation with its principal places of business at 1090 Horsham Road, North Wales, Maryland. It is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., and has offices located at 650 Cahill Road, Sellersville, Maryland 18960 and 1090 Horsham Road, North Wales, Maryland 19454. Teva regularly conducts significant business in the State of Maryland.

9. Pfizer, Wyeth, Schwarz, Pliva, and Teva, identified supra, inclusive, and each of them, may be referred to in this Complaint collectively as the “Defendants”.

10. At all times relevant hereto, the Defendants were in the regular business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, branded and or generic Reglan/metoclopramide, directly or indirectly, through third parties, as successor in interest, or other related entities, in the State of Maryland, for which they each derived significant and regular income.

11. At all times relevant hereto, the Defendants were acting by and through their agents, servants and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf, for which their principals are vicariously responsible.

VENUE AND JURISDICTION

12. The amount in controversy exceeds seventy-five thousand dollars ($75,000.00) exclusive of costs and interest, and diversity jurisdiction exists pursuant to 28 U.S.C. § 1391.

13. Venue is invoked in the United States District Court for the District of Maryland, Southern Division, as the cause of action giving rise to this Complaint occurred in Prince George's County, Maryland, where the plaintiff ingested the drug manufactured and sold by the defendants.

14. This court has jurisdiction over the Defendants because they have offices in Maryland and/or regularly solicited and transacted business in the State of Maryland through their pharmaceutical sales representatives and/or were engaged in regularly testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities Reglan/metoclopramide in the State of Maryland and with a reasonable expectation that the medication would be used or consumed in the State of Maryland.

FACTUAL BACKGROUND REGARDING REGLAN/METOCLOPRAMIDE

15. This case involves the long term ingestion of Reglan/metoclopramide by the Plaintiff as prescribed by her physician(s). Reglan/metoclopramide is a prescription medication classified as a GI stimulant, antiemetic and Dopaminergic blocking agent. It is indicated for short-term therapy for symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

16. Reglan/metoclopramide is indicated for treatment use of no greater than twelve (12) weeks; however, Defendants represented that Reglan/metoclopramide was safe for use to treat nausea and or esophageal reflux for durations that exceeded 12 weeks.

17. Patients who use Reglan/metoclopramide for long periods (exceeding 12 weeks) are at a significant and unreasonably dangerous increased risk of developing a severe and permanent neurological movement disorder, known as tardive dyskinesia and/or akathisia.

18. Other serious side effects that may be caused by ingesting Reglan/metoclopramide for longer periods of time include, but are not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism.

19. Patients who use Reglan/metoclopramide for long periods (greater than 12 weeks) who are not able to effectively metabolize it are at a greater risk of developing these serious and permanent injuries.

20. Tardive Dyskinesia and Akathisia are serious side effects associated with the ingestion of Reglan/metoclopramide and are debilitating neurological disorders that often result in involuntary and uncontrollable movements of the head, neck, face, arms, legs and/or trunk, as well as, involuntary facial grimacing and tongue movements, including tongue thrusting, tongue chewing and/or other involuntary movements.

21. Presently, there is no known cure for Tardive Dyskinesia or Akathisia.

FACTUAL BACKGROUND REGARDING PLAINTIFF

22. Beginning in March 2006, Plaintiff was prescribed Reglan/metoclopramide at a dosage of 10 mg to treat stomach problems by her physician(s), which she took until about January 2007.

23. In 2007, Ms. Gross was exhibiting abnormal movements which have since been linked to her use of Reglan/metoclopramide. She was examined by her physician and presented with symptoms of confusion, memory difficulty, uncontrollable involuntary movements and gait disorder, among others. She was subsequently diagnosed with Tardive Dyskinesia.

24. During the time of her ingestion of Reglan/metoclopramide Plaintiff remained at all times unaware of the potential risks, side effects and/or relationship between the continued ingestion of Reglan/metoclopramide as prescribed and the physical symptoms that she was developing.

25. At no time prior to 2006, nor during the time she consumed the drug, was Plaintiff knowledgeable or informed of the dangerous side effects associated with prolonged exposure to Reglan/metoclopramide.

26. Based upon information and belief Plaintiff's symptoms of Tardive Dyskinesia and Akathisia associated with the use of Reglan/metoclopramide, went unrecognized until on or about 2008.

27. Upon information and belief, in prescribing Reglan/metoclopramide to Plaintiff on a long-term basis, her prescribing physician(s) relied upon information published in the package inserts and/or the Physician's Desk Reference ("PDR") or otherwise disseminated by the Reference Listed Drug Company ("RLD") and/or the New Drug Application Holder ("NDA Holder"). Upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Reglan/metoclopramide to Plaintiff in the same or similar manner, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

28. Plaintiff's use of Reglan/metoclopramide occurred without substantial change in the condition of the drug between the time of design and manufacture and the time she ingested said drug as prescribed and directed.

29. Plaintiff ingested Reglan/metoclopramide, as prescribed, that resulted in unnecessary and unreasonably dangerous overexposure to the drug causing her to suffer serious, permanent and disabling injuries, including injuries of and/or associated with the central nervous and extrapyramidal motor systems (EPS), specifically Tardive Dyskinesia and Akathisia.

30. Had the Plaintiff known of the risks associated with long-term ingestion of Reglan/metoclopramide she would not have taken the drug.

31. Plaintiff's injuries, came about as a foreseeable and proximate result of the Defendants' dissemination of inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the potential effects of exposure to and long-term ingestion of Reglan/metoclopramide to the medical community, and thereby foreseeable users of the drug, including the Plaintiff. Accordingly, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide to Plaintiff in a manner which they would not have, had they known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

32. In February 2009, having recognized the inadequate nature of the Defendants' label and warnings, the United States Food and Drug Administration ("FDA") issued an advisory requiring the addition of a Boxed Warning for Reglan/metoclopramide. This new warning, appearing at the top of the label, spells out that, "Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible...." Additionally , the new Boxed Warning now tells physicians and patients that "Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases..." Finally, the FDA is now requiring that Manufacturers/Defendants implement a Risk Evaluation and Mitigation Strategy because the FDA has determined that the use of Reglan/metoclopramide "pose[s] a serious and significant public health concern requiring the distribution of a Medication Guide."

The Medication Guide, sets out the risks of the drug and is to be given to all users and, "is necessary for the patient's safe use of Reglan (metoclopramide)..." Unfortunately, neither the Boxed Warning nor the Medication Guide was available to Plaintiff or her prescribing physician(s).

LIABILITY OF ALL DEFENDANTS

33. This case involves the Defendants' failure to warn physicians and/or the medical community of information that was within the Defendants' extensive knowledge or possession, that Reglan/metoclopramide, when taken for long periods of time (i.e. for longer than 12 weeks) could and did cause serious, permanent and debilitating side effects, including tardive dyskinesia and akathisia.

34. The Defendants, as pharmaceutical manufacturers, are in the business of formulating, manufacturing, testing, packaging, providing warnings for marketing, distributing and selling Reglan/metoclopramide in its brand name and/or generic form.

35. Defendants widely advertised that Reglan/metoclopramide was a safe and effective treatment for diabetic gastroparesis, gastroesophageal reflux disease (GERD) and other gastrointestinal disorders.

36. Defendants jointly and severally marketed, manufactured and distributed Reglan/ metoclopramide and encouraged the long term prescribing and use of this drug, and misrepresented the effectiveness of this drug and concealed the drug's dangerous side effects.

37. The Defendants developed, manufactured, tested, packaged, marketed, sold and/or distributed Reglan/metoclopramide to the general public despite knowledge that the design, manufacturing and/or side effect defects associated with this drug unreasonably caused, and/or had the potential to unreasonably cause, injuries with the foreseeable and/or prescribed use of the drug.

38. The Defendants, as pharmaceutical manufacturers, had prior knowledge and information within their possession that indicated Reglan/metoclopramide was defective and unreasonably dangerous, including, the fact that it was capable of causing severe physical, mental and emotional injuries to those who ingested the drug.

39. Reglan/metoclopramide as manufactured was defective and not reasonably safe as

designed because of the foreseeable and undisclosed risks associated with the long-term ingestion of the drug and which were not made known to the prescriber and ultimately thereby to the user/consumer, in this case the Plaintiff, Ms. Gross. Accordingly, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide to Plaintiff in a dissimilar manner than the physician(s) would have, had the physician(s) been reasonably notified by the Defendants of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

40. The Defendants as pharmaceutical manufacturers knew or should have known that Reglan/metoclopramide was defective and unreasonably dangerous and that it was expected to and did reach consumer(s), including the Plaintiff without substantial change in the drug.

41. The Defendants, through their unique knowledge and expertise of Reglan/metoclopramide and through advertising statements, promotional materials and other communications, falsely represented to physicians, the medical community and thereby ultimately consumers (Plaintiff) that Reglan/metoclopramide was safe for its intended use and was free from design, safety and/or manufacturing defects.

42. The Defendants knew through testing, adverse event reporting and/or other means that Reglan/metoclopramide created a high risk of bodily injury and serious harm to those who ingested the drug as prescribed over extended time periods (over 12 weeks duration).

43. The Defendants, as pharmaceutical manufacturers, failed to provide timely and adequate post-marketing warnings or instructions regarding the risks of injury from Reglan/metoclopramide associated with long term use as commonly prescribed, while knowing (or on constructive notice) that the design, manufacturing, and safety defects associated with the drug had an unreasonable risk of causing severe neurological disorders, such as Tardive Dyskinesia.

44. Despite such knowledge, the Defendants, knowingly and deliberately, failed to warn the medical community, and thereby ultimately Plaintiff, of the extreme risk of physical injury occasioned by the defects of Reglan/metoclopramide.

45. Defendants have a duty to ensure their warnings to the medical community are accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to report any data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

46. Defendants had a duty to exercise the care of an expert and in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing and sale of Reglan/metoclopramide to ensure the safety of the drug and to ensure that the medical community and thereby ultimately the consuming public obtained accurate information and instructions for the safe use or non-use of said drug.

47. The Defendants failed to discharge this duty by distributing a defective drug into the stream of commerce without warning or notice of the foreseeable and unreasonably dangerous side effects. Defendants' breach of their duties exposed Plaintiff to a high risk of bodily injury and serious harm.

48. By withholding information of known design and manufacturing defects and concealing said issues, the Defendants created a false sense of security for users of said drug product.

49. Reglan/metoclopramide was defective and unreasonably dangerous to foreseeable users and patients, including the Plaintiff who ingested said drug in a prescribed and reasonably foreseeable manner.

50. The Defendants breached their duties, and proximately caused, through a defective product, severe damage.

51. The defect(s) directly and proximately caused Plaintiff severe and permanent injuries, in that it or they directly and in natural and continuous sequence produced and contributed substantially to Plaintiff's injuries.

52. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiff ingested Reglan/metoclopramide as prescribed and for periods in excess of 12 weeks duration which unbeknownst to her and, upon information and belief, was unbeknownst to her prescribing physician(s) was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

53. As a direct and proximate result of the acts and omissions of the Defendants' conduct, Plaintiff suffered injury, harm and economic loss, including medical bills, medical expenses, including permanent and substantial physical disability.

54. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiff suffered among other things extreme emotional distress, anguish, physical and mental suffering, weakness and involuntary shaking, tremors and continuous involuntary movements of her body rendering her physically and permanently disabled.

55. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiff experienced extreme embarrassment, shame, anguish, anxiety, and an inability to care for herself.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

CAUSES OF ACTION

COUNT I: NEGLIGENCE
WYETH (N/K/A PFIZER)

56. Plaintiff incorporates by reference all of the above paragraphs.

57. Defendant, Wyeth developed and branded the pharmaceutical drug Reglan/metoclopramide. Defendant Pfizer, Inc. has merged and/or acquired Co-Defendant Wyeth.[1]

58. Defendant, Wyeth is the successor in interest to A.H. Robins Company, Inc., which first obtained approval by the FDA to distribute metoclopramide, under the brand name "Reglan" under the FDA's New Drug Application (NDA) schema in 1983.

59. Defendant, Wyeth manufactured, marketed and distributed Reglan/metoclopramide and/or metoclopramide HCL, through its various divisions and/or subsidiaries, including Wyeth-Ayerst Laboratories Division in St. Davids, Maryland and through its ownership of "ESI". [2]

60. At all times material hereto, Defendant, Wyeth was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor in interest or other related entities the drug Reglan/metoclopramide.

61. On or before Plaintiff was first prescribed Reglan/metoclopramide, Defendant, Wyeth knew that it must fully disclose material safety data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling, including warnings about risks and side effects, and test results involving animal studies, clinical studies and the drug's bioavailability.

[1] Upon information and belief, Wyeth was the holder of multiple NDAs for Reglan, metoclopramide and metoclopramide HCL.

[2] Upon information and belief, ESI was a former subsidiary which merged into Wyeth on or about December 15, 1998.

62. On or before Plaintiff was first prescribed Reglan/metoclopramide, Defendant, Wyeth knew that the data and information would be relied upon by the medical community, physicians, Plaintiff and other foreseeable users of Reglan/metoclopramide once the NDA was approved and Wyeth was listed as the Reference Listed Drug Company ("RLD") for the drug.

63. On or before Plaintiff was first prescribed Reglan/metoclopramide, Defendants as the NDA Holder and/or RLD companies were aware of the serious side effects caused by the long-term ingestion of Reglan/metoclopramide including but not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism.

64. On or before Plaintiff was first prescribed Reglan/metoclopramide, Defendant, Wyeth had actual knowledge through their own studies and studies by independent investigators, that doctors frequently prescribed Reglan/metoclopramide for long-term use that was not safe for patients.

65. On or before Plaintiff was first prescribed Reglan/metoclopramide, Defendant, Wyeth through their own studies and studies by independent investigators, that nearly one-third of all patients who used Reglan/metoclopramide received it on doctor's prescriptions for 12 months or longer, rather than 12 weeks or less.

66. On or before Plaintiff was first prescribed Reglan/metoclopramide, Defendant, Wyeth had actual knowledge, through research by independent investigators, that the risk of tardive dyskinesia and other extrapyramidal side effects (EPS) of Reglan/metoclopramide in patients who receive the drug for 12 weeks or longer is approximately 100 times greater than disclosed in package inserts and the PDR.

67. On or before Plaintiff was first prescribed Reglan/metoclopramide, Defendant, Wyeth knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize it and that as a foreseeable consequence of their inability to effectively metabolize, those patients have a greater risk of developing serious and permanent injuries.

68. Despite information as to the significant risks and side effects associated with long-term (greater than 12 weeks) Reglan/metoclopramide ingestion Defendant, Wyeth failed to correct their monograph and/or disclose that knowledge to the medical community, Plaintiff and other foreseeable users. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

69. Defendant, Wyeth knew that generic drug manufacturers customarily copy verbatim the package insert for the name brand prescription drug product to give the impression that the information contained in the package inserts accompanying their own generic prescription drugs is accurate and not misleading.

70. Defendant, Wyeth knew that the generic drug manufacturers also typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

71. Defendant, Wyeth knew that physicians commonly consult the information disseminated by the name brand manufacturer, in the PDR or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients.

72. Defendant, Wyeth knew that physicians would rely upon the information disseminated to them by the name brand manufacturer, regardless of whether the prescriptions might be filled with either

the name brand product, Reglan, or generic Reglan/metoclopramide, and that many patients, in accordance with those prescriptions, would be likely to ingest generic Reglan/metoclopramide.

73. Defendant, Wyeth was aware that under the FDA schema, if the FDA approves a label change as requested by an ANDA holder, the NDA holder (also referred to as the RLD company) must also amend its label.

74. Defendant, Wyeth knew that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long-term side effects on ingesting the drug.

75. Defendant, Wyeth failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short-term and long-term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

76. Defendant, Wyeth owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan/metoclopramide, to exercise reasonable care to ensure that they did not create unreasonable risks of personal injury to others.

77. Defendant, Wyeth failed to review all adverse drug event information[3] and to report any information bearing upon the adequacy and accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan/metoclopramide.

78. Defendant, Wyeth failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan/metoclopramide for periods of time in excess of 12 weeks duration.

[3] Defendants are required to review all adverse drug experience information obtained or otherwise received...from any source...including derived from post marketing clinical investigations, postmarketing epidemiological/surveillance studies, reports from the scientific literature, and unpublished scientific reports. 21 C.F.R § 317.80(b). Mensing v. Wyeth, Inc., U.S. Court of Appeals 08-3850 (8th Cir. 11/27/2009).

79. Defendant, Wyeth, was negligent and breached its duties owed to the Plaintiff as a user and consumer with respect to the manufacture and sale of Reglan/metoclopramide, as set forth otherwise herein and for reasons including, but not limited to the following:

a) Failing to reasonably design, manufacture, test, inspect, market, sell and/or distribute, Reglan/metoclopramide so as to avoid the aforementioned risks to individuals;

b) Failing to reasonably accompany the drug with adequate warnings, instructions and updates regarding the adverse and permanent side effects including death (particularly with foreseeable long term use), despite Defendant, Wyeth's knowledge of the defects and risks associated with Reglan/metoclopramide ingestion;

c) Failing to reasonably and accurately represent to the prescribing physician(s) and ultimately thereby users and consumers, that the drug can cause central nervous system side effects and significant and permanent extrapyramidal symptoms, particularly with foreseeable long term use;

d) Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Reglan/metoclopramide, and failing to monitor all relevant scientific literature related to Reglan/metoclopramide;

e) Failing to adequately and reasonably inform the medical community that Reglan/metoclopramide was unreasonably dangerous for long-term use, despite having knowledge, through their own studies and studies by independent investigators, that physicians frequently prescribed Reglan/metoclopramide for long-term use;

f) Failing to reasonably and sufficiently disclose information in package inserts for Reglan/metoclopramide or through the Physician's Desk Reference (PDR), the risks of Tardive Dyskinesia and other extra pyramidal side effects of Reglan/metoclopramide, including, but not limited to the increased risks for patients who receive the drug for 12 weeks or longer;

g) Failing to reasonably and promptly correct and/or amend the package inserts, PDR monographs, and literature regarding the risks of long term ingestion of Reglan/metoclopramide, once the side effects became actually or constructively known; with the knowledge that this information would be disseminated to physicians who would rely upon that information in their decisions concerning the prescription of drug therapy for their patients;

h) Failing to reasonably and properly conduct and report adequate post-marketing surveillance and testing to determine the safety of the product, particularly with foreseeable long-term use, despite Defendant Wyeth's knowledge of the defects and risks associated with Reglan/metoclopramide ingestion;

i) Failing to reasonably and adequately warn that the long term use of Reglan/metoclopramide may result in side effects such as Depression with Suicidal Ideation, Akathisia, Akinesia, Tardive Dyskinesia, Tardive Dystonia, Visual Disturbances, etc., and that these side effects were permanent in nature;

j) Willfully and deliberately failing to adequately disclose all actual and/or constructively known risks regarding Reglan/metoclopramide and in doing so, acted with a conscious disregard of Plaintiff's safety and/or welfare.

80. The negligence described above directly and proximately caused Plaintiff severe and permanent injuries, in that it or they directly and in natural and continuous sequence produced and contributed substantially thereto, including, but not limited to the fact that Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II: BREACH OF WARRANTY
WYETH (N/K/A PFIZER)

81. Plaintiff incorporates by reference all of the above paragraphs.

82. Defendant, Wyeth's predecessor-in-interest, A.H. Robins Company, Inc., expressly warranted to physicians that Reglan/metoclopramide was and is safe for long term use.

83. As successor-in-interest to A.H. Robins Company, Inc., Defendant, Wyeth is legally responsible for the conduct, fraudulent and negligent acts, intentional and willful omissions and misleading representations and warranties made by A.H. Robins Company, Inc. concerning the safety and adequacy of Reglan/metoclopramide and all liabilities stemming therefrom.

84. Through its promotional statement(s) and product literature Defendant expressly warranted to the medical community and thereby ultimately the user/consumer (Plaintiff) that Reglan/metoclopramide was safe and capable of treating gastrointestinal disorders over an extended period of time (i.e. over 12 weeks), despite Defendant's knowledge to the contrary.

85. Defendant knew or should have known that its warranties regarding safety forlong-term use would be relied upon by the medical community which included ordinary, reasonable and prudent physicians who would share that information with others in the medical community and that eventually prescribing physicians and the public (including Plaintiff) would come to rely and did rely upon Defendant's express warranties about Reglan/metoclopramide's safety for long-term use.

86. Defendant's express warranties about the safety of Reglan/metoclopramide for long-term use were false and intentionally misleading.

87. Despite knowledge to the contrary Defendant continued to promote, sell and market the safety of Reglan/metoclopramide, while having knowledge of the design, manufacturing, safety defects and risk that it posed to the user/consumer of developing severe neurological side effects such as Tardive Dyskinesia with prolonged use of the drug.

88. Defendant through its marketing, promoting, selling and distribution of Reglan/metoclopramide represented that its drug product was of merchantable quality and safe and fit for its intended use of treating gastrointestinal symptoms such as gastroesophageal reflux and gastroparesis. At the same time Defendant continued to conceal and fail to warn of the risks and side effects of neurological disorders such as Tardive Dyskinesia and Akathisia which were associated with long-term use of Reglan/metoclopramide and continued to impliedly warrant the medical soundness of the drug product to the medical community/physicians and thereby ultimately the general public, user/consumer (Plaintiff).

89. Plaintiff and her prescribing physician(s) reasonably relied on the presumption that the Defendant would provide notice, disclosure or warnings of any risks associated with Reglan/metoclopramide's merchantability, quality, safety and fitness for its intended use. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

90. Contrary to such implied warranties, Reglan/metoclopramide was not of merchantable quality or safe or fit for its intended use, because the drugs were and are unreasonably dangerous and unfit for the ordinary, intended and foreseeable use due to the adverse side effects.

91. As a direct and proximate result of the Defendant's breach of warranty, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III: MISREPRESENTATION AND FRAUD
WYETH (N/K/A PFIZER)

92. Plaintiff incorporates by reference all of the above paragraphs.

93. Defendant, Wyeth intentionally and negligently disseminated misleading information to physicians across the country, through the PDR, about the risks of long-term ingestion of Reglan/metoclopramide and the increased risk of extrapyramidal side effects, including tardive dyskinesia and akathisia.

94. Defendant misrepresented the soundness and reliability of Reglan/metoclopramide to physicians and the medical community and thereby ultimately the general public, user/consumer (Plaintiff) through promotional and marketing campaigns. It misrepresented that the drug was safe and effective when used as prescribed , when in fact, it was dangerous to the health of patients. Defendant continued these misrepresentations for an extended period of time, without disclosing material information that was available to them.

95. Defendant concealed the design, manufacturing and safety defects from the public by withholding information pertaining to the design, manufacturing, safety defects and risks of severe and permanent neurological side effects related to the ingestion and long-term use of Reglan/metoclopramide, while knowingly presenting to the medical community and thereby ultimately the general public, user/consumer (Plaintiff) that the drug was sound and reliable.

96. Defendant knew of the risks that Reglan/metoclopramide presented to users/ consumers when they unknowingly ingested the prescribed drug product for periods in excess of 12 weeks duration, and failed to inform the prescribing physicians of that risk.

97. Defendant failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe or unsafe use of Reglan/metoclopramide and otherwise failed to exercise reasonable care in transmitting information to the medical community and thereby ultimately to the general public including Plaintiff.

98. Defendant made these representations concerning Reglan/metoclopramide in the course of their business as designers, manufacturers and distributors of the drug.

99. Such representations were made by the Defendant with the intent to defraud and/or deceive the medical community and thereby ultimately the user/consumer of Reglan/metoclopramide

and with the knowledge and intent to induce reliance upon these representations and use of said drug product.

100. Defendants knowingly concealed from physicians material facts bearing on the interpretation of package insert disclosures that exposure to Reglan/metoclopramide can lead to tardive dyskinesia and other extrapyramidal side effects, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than 12 weeks "cannot be recommended".

101. Defendants concealed the fact that earlier false information disseminated by A.H. Robins Company and/or Wyeth representing long-term Reglan/metoclopramide therapy to be reasonably safe, was unscientific and false.

102. Defendants concealed the fact that Reglan/metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to tardive dyskinesia and other extrapyramidal side effects with approximately the same high frequency, particularly in longer term use as other neuroleptic drugs and that epidemiological studies have consistently confirmed this expectation.

103. Defendants also concealed the fact that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroparesis and/or other gastric disorders with Reglan/metoclopramide for longer than 12 weeks is unlikely to be reasonably safe.

104. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV: STRICT LIABILITY
WYETH (N/K/A PFIZER)

105. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

106. Plaintiff is in the class of persons that Defendants Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (n/k/a Pfizer) should reasonably foresee as being subject to the harm caused by defectively designed pharmaceuticals, including the Reglan/Metoclopramide at issues in this lawsuit, insofar as Plaintiff Shirley Gross was the type of person for whom the Reglan/Metoclopramide was intended to be used.

107. Defendants, Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (n/k/a Pfizer), which are engaged in the business of selling the products, manufactured and supplied pharmaceuticals, including the Reglan/Metoclopramide at issues in this lawsuit, and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

108. The Reglan/Metoclopramide supplied to Plaintiff was defective in design and formulation and unreasonably dangerous when it left the hands of Defendants, the manufacturers and suppliers, and they reached the user and consumer of the products, Plaintiff, without substantial alteration in the condition in which they were sold.

109. The Reglan/Metoclopramide manufactured by Defendants was unreasonable and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding these products.

110. Defendants', Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (n/k/a Pfizer), Reglan/Metoclopramide was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results of such studies.

111. Defendants', Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (n/k/a Pfizer) Reglan/Metoclopramide was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their Reglan/Metoclopramide, they failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

112. The product defects alleged above were a substantial contributing cause of the injuries suffered by Plaintiff. Specifically, Reglan/Metoclopramide caused Plaintiff to suffer permanent and disabling injuries, specifically Tardive Dyskinesia. Plaintiff will also require future medical care. In addition, Plaintiff has suffered mental distress and anguish and has suffered permanent impairment.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V: STRICT PRODUCTS LIABILITY: FAILURE TO WARN WYETH (N/K/A PFIZER)

113. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

114. Defendants, Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (n/k/a Pfizer), manufactured Reglan/Metoclopramide and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

115. Defendants', Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (n/k/a Pfizer), Reglan/Metoclopramide was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results.

116. Defendants', Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (n/k/a Pfizer), Reglan/Metoclopramide was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their Reglan/Metoclopramide, they failed to provide adequate warnings to the medical community and patients, and continued to promote long term use of Reglan/Metoclopramide as safe and effective.

117. The defective warnings and labeling on Reglan/Metoclopramide was the substantial factor in bringing about the injuries to the Plaintiff.

118. As the direct and proximate cause of the defective condition of Reglan/Metoclopramide as manufactured and/or supplied by Defendants, and specifically their failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VI: NEGLIGENCE
SCHWARZ PHARMA

119. Plaintiff incorporates by reference all of the above paragraphs.

120. Based upon information and belief Defendant, Schwarz purchased from Defendant, Wyeth the rights and liabilities associated with Reglan/metoclopramide and the terms of which, obligated Schwarz to accept responsibility for claims related to the ingestion or use of Reglan/metoclopramide.

121. Based upon information and belief Defendant, Schwarz entered into an indemnification agreement with Wyeth over the purchase of the innovator, Wyeth's, Reglan, which included disclosure of clinical studies on Reglan/metoclopramide that were not publicly available.

122. It is further believed that Defendant, Schwarz acquired Defendant Wyeth's Reglan/metoclopramide assets and liabilities while Wyeth was involved in ongoing litigation regarding Reglan/metoclopramide and as such agreed to indemnify Wyeth against all claims related to the ingestion of the drug. Schwarz knew or should have known that the NDA label for Reglan/metoclopramide (Wyeth's label) misrepresented the safety of the drug, withheld warnings of the known side effects of the drug and knew or should have known of the safety issues involved.

123. Under the FDA schema, Defendant, Schwarz was and remains the RLD and/or NDA holder for Reglan/metoclopramide.

124. At all times material hereto, Defendant, Schwarz, as the NDA Holder and/or RLD companies, was aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression which suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism.

125. Defendant, Schwarz represented that Reglan/metoclopramide was safe for use to treat gastritis/gastroesophageal reflux knowing that the drug was not safe for that purpose and was dangerous to the health and body of the user of said drug, which in this case was the Plaintiff.

126. Defendant, Schwarz represented that Reglan/metoclopramide caused minimal side effects knowing that the drug caused central nervous system side effects, and extrapyramidal symptoms, among other side effects, far more frequently than represented. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

127. Defendant, Schwarz knew or should have known through its own studies and studies by independent investigators, that doctors frequently prescribed Reglan/metoclopramide for long-term use and that it was not safe for patients.

128. Defendant, Schwarz knew or should have known, through its own studies and studies by independent investigators, that nearly one-third of all patients who used Reglan/metoclopramide received it on doctor's prescriptions for twelve (12) months or longer, rather than twelve (12) weeks or less.

129. Defendant, Schwarz knew or should have known through research by independent investigators, that the risk of tardive dyskinesia and other extrapyramidal side effects (EPS) of Reglan/metoclopramide in patients who receive the drug for twelve (12) weeks or longer is approximately 100 times greater than disclosed in package inserts and the PDR.

130. Defendant, Schwarz knew or should have known through its expertise or through the exercise of reasonable care that many patients who use Reglan/metoclopramide are not able to effectively metabolize it and that as a foreseeable consequence of their inability to effectively metabolize, those patients have a greater risk of developing serious and permanent injuries.

131. Thereby, Defendant, Schwarz, was negligent and breached duties owed to Plaintiff as user and consumer with respect to its manufacture and sale of Reglan/ metoclopramide, as set forth otherwise herein and for reasons including, but not limited to the following:

a) Failing to reasonably design, manufacture, test, inspect, market, sell and/or distribute, Reglan/metoclopramide so as to avoid the aforementioned risks to individuals;

b) Failing to reasonably accompany the drug with adequate warnings, instructions and updates regarding the adverse and permanent side effects , including death (particularly with foreseeable long term use), despite Defendant, Schwarz's knowledge of the defects and risks associated with Reglan/metoclopramide ingestion;

c) Failing to reasonably and accurately represent to physicians and ultimately thereby users and consumers, that the drug can cause central nervous system side effects and significant and permanent extrapyramidal symptoms, particularly with foreseeable long term use;

d) Failing to conduct adequate and reasonable testing on the risks and side effects associated with long term ingestion of Reglan/metoclopramide and conduct post-marketing surveillance to determine the safety of Reglan/metoclopramide, and failing to monitor all relevant scientific literature related to Reglan/metoclopramide;

e) Failing to adequately and reasonably inform the medical community that Reglan/metoclopramide was unreasonably dangerous for long-term use, despite having knowledge, through their own studies and studies by independent investigators, that physicians frequently prescribed Reglan/metoclopramide for long-term use;

f) Failing to reasonably and sufficiently disclose information in package inserts for Reglan/metoclopramide or through the Physician's Desk Reference (PDR), the risks of Tardive Dyskinesia and other extra pyramidal side effects of Reglan/metoclopramide, including, but not limited to the increased risks for patients who receive the drug for 12 weeks or longer;

g) Failing to reasonably and promptly correct and/or amend the package inserts, PDR monographs, and literature regarding the risks of long term ingestion of Reglan/metoclopramide, once the side effects became actually or constructively known; with the knowledge that this information would be disseminated to physicians who would rely upon that information in their decisions concerning the prescription of drug therapy for their patients;

h) Failing to reasonably and properly conduct and report adequate post-marketing surveillance and testing to determine the safety of the product, particularly with

foreseeable long-term use, despite Defendant Schwarz's knowledge of the defects and risks associated with Reglan/metoclopramide ingestion;

i) Failing to reasonably and adequately warn that the long term use of Reglan/metoclopramide may result in side effects such as Depression with Suicidal Ideation, Akathisia, Akinesia, Tardive Dyskinesia, Tardive Dystonia, Visual Disturbances, etc., and that these side effects were permanent in nature;

j) Willfully and deliberately failing to adequately disclose all actual and/or constructively known risks regarding Reglan/metoclopramide and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare.

132. The negligence described above directly and proximately caused Plaintiff severe and permanent injuries, in that it or they directly and in natural and continuous sequence produced, contributed substantially or enhanced the Plaintiff's injuries, harm including permanent and substantial physical disabilities, and the expenses attributable thereto, including but not limited to the fact that Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

133. Defendant, Schwarz, individually and as accepting and purchasing Wyeth's liability, intentionally, recklessly, and/or negligently disseminated misleading information to physicians and patient's across the country, including the Plaintiff, through but not limited to its drug representatives, drug advertisements and marketing, drug package inserts and/or its published version found in the PDR, about the risks of long term ingestion of Reglan/metoclopramide and/or of the increased risk or lack thereof of extrapyramidal side effects, including Tardive Dyskinesia.

134. Defendant, Schwarz, individually and as accepting and purchasing Defendant, Wyeth's liability, is accordingly liable for the intentional, reckless, and/or negligent misrepresentations and

omissions that were made willfully, wantonly, recklessly, and/or negligently by Defendant, Wyeth or on their own behalf to Plaintiff to induce purchase of their drug.

135. Defendant, Schwarz, individually and as accepting and purchasing Defendant, Wyeth's liability is liable for Wyeth's as well as its own intentional reckless, and/or negligent conduct. Plaintiff came to rely upon the safety and soundness of its drug Reglan/metoclopramide and so failed to appreciate or have knowledge of the risk associated with long-term ingestion of said drug.

136. Defendant, Schwarz individually and as accepting and purchasing Wyeth's liability is liable for Wyeth's conduct as well as their own conduct for the intentional, reckless, and/or negligent omission, concealment and failure to warn of the design and manufacturing defects which caused Plaintiff to suffer injury, harm and economic loss as alleged herein, including permanent and substantial physical disability as well as expenses attributable thereto.

137. The Defendant breached its duties, and proximately caused through its acts of negligence, severe and permanent damage to Plaintiff.

138. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff ingested Reglan/metoclopramide as prescribed for periods in excess of 12 weeks duration and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VII: BREACH OF WARRANTY
SCHWARZ

139. Plaintiff incorporates by reference all of the above paragraphs.

140. Through its promotional statement(s) and product literature Defendant expressly warranted to the medical community and thereby ultimately the user/consumer (Plaintiff) that Reglan/metoclopramide was safe and capable of treating gastrointestinal disorders over an extended period of time (i.e. over 12 weeks), despite Defendant's knowledge to the contrary.

141. Defendant knew or should have known that its warranties regarding safety for long-term use would be relied upon by the medical community which included ordinary, reasonable and prudent physicians who would share that information with others in the medical community and that eventually prescribing physicians and the public (including Plaintiff) would come to rely and did rely upon Defendant's express warranties about Reglan/metoclopramide's safety for long-term use.

142. Defendant's warranties about the safety of Reglan/metoclopramide for long-term use were false and intentionally misleading.

143. Despite knowledge to the contrary Defendant continued to promote, sell and market the safety of Reglan/metoclopramide, while having knowledge of the design, manufacturing, safety defects and risk that it posed to the user/consumer of developing severe neurological side effects such as Tardive Dyskinesia with prolonged use of the drug.

144. Defendant through its marketing, promoting, selling and distribution of Reglan/metoclopramide represented that its drug product was of merchantable quality and safe and fit for its intended use of treating gastrointestinal symptoms such as gastroesophageal reflux and gastroparesis. At the same time Defendant continued to conceal and fail to warn of the risks and side effects of neurological disorders such as Tardive Dyskinesia and Akathisia which were associated with long-term use of Reglan/metoclopramide and continued to impliedly warrant the medical soundness of the drug product to the medical community/physicians and thereby ultimately the general public, and Plaintiff.

145. Plaintiff and her prescribing physician(s) reasonably relied on the presumption that the Defendant would provide notice, disclosure or warnings of any risks associated with Reglan/metoclopramide's merchantability, quality, safety and fitness for its intended use. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

146. Contrary to such implied warranties, Reglan/metoclopramide was not of merchantable quality or safe or fit for its intended use, because the drugs were and are unreasonably dangerous and unfit for the ordinary, intended and foreseeable use due to the adverse side effects.

147. As a direct and proximate result of the Defendant's breach of warranty, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VIII: MISREPRESENTATION AND FRAUD
SCHWARZ

148. Plaintiff incorporates by reference all of the above paragraphs.

149. Defendant intentionally and negligently disseminated misleading information to physicians across the country, through the PDR, about the risks of long-term ingestion of Reglan/metoclopramide and the increased risk of extrapyramidal side effects, including tardive dyskinesia.

150. Defendant misrepresented the soundness and reliability of Reglan/metoclopramide to physicians and the medical community and thereby ultimately the general public through promotional and marketing campaigns. It misrepresented that the drug was safe and effective when used as prescribed, when in fact, it was dangerous to the health of patients. Defendant continued these misrepresentations for an extended period of time, without disclosing material information that was available to them.

151. Defendant concealed the design, manufacturing and safety defects from the public by withholding information pertaining to the design, manufacturing, safety defects and risks of severe and permanent neurological side effects related to the ingestion and long-term use of Reglan/metoclopramide, while knowingly presenting to the medical community and thereby ultimately the general public that the drug was sound and reliable.

152. Defendant knew or should have known of the risks that Reglan/metoclopramide presented to users/consumers when they unknowingly ingested the drug product as prescribed.

153. Defendant failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of Reglan/metoclopramide and otherwise failed to exercise reasonable care in transmitting information to the medical community and thereby ultimately to the general public, user/consumer including Plaintiff. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

154. Defendant made these representations concerning Reglan/metoclopramide in the course of their business as designers, manufacturers and distributors of the drug at issue.

155. Such representations were made by the Defendant with the intent to defraud and/or deceive the medical community and thereby ultimately the user/consumer of Reglan/metoclopramide

and with the knowledge and intent to induce reliance upon these representations and use of said drug product.

156. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IX: STRICT LIABILITY
SCHWARZ

157. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

158. Plaintiff is in the class of persons that Defendant Schwarz Pharma, Inc. should reasonably foresee as being subject to the harm caused by defectively designed pharmaceuticals, including the Reglan/Metoclopramide at issue in this lawsuit, insofar as Plaintiff Shirley Gross was the type of person for whom the Reglan/Metoclopramide was intended to be used.

159. Defendant Schwarz Pharma, Inc., which is engaged in the business of selling the products, manufactured and supplied pharmaceuticals, including the Reglan/Metoclopramide at issue in this lawsuit, and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

160. The Reglan/Metoclopramide supplied to Plaintiff was defective in design and formulation and unreasonably dangerous when it left the hands of Defendant, the manufacturers and suppliers, and they reached the user and consumer of the products, Plaintiff, without substantial alteration in the condition in which they were sold.

161. The Reglan/Metoclopramide manufactured by the Defendant was unreasonable and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding these products.

162. Defendant Schwarz Pharma, Inc.'s Reglan/Metoclopramide was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results of such studies.

163. Defendant Schwarz Pharma, Inc.'s Reglan/Metoclopramide was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their Reglan/Metoclopramide, they failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

164. The product defects alleged above were a substantial contributing cause of the injuries suffered by Plaintiff. Specifically, Reglan/Metoclopramide caused Plaintiff to suffer permanent and disabling injuries, specifically Tardive Dyskinesia. Plaintiff will also require future medical care. In addition, Plaintiff has suffered mental distress and anguish and has suffered permanent impairment.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT X: STRICT PRODUCTS LIABILITY: FAILURE TO WARN SCHWARZ

165. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

166. Defendant Schwarz Pharma, Inc. manufactured Reglan/Metoclopramide and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

167. Defendant Schwarz Pharma, Inc.'s Reglan/Metoclopramide was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results.

168. Defendant Schwarz Pharma, Inc.'s Reglan/Metoclopramide was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their Reglan/Metoclopramide, they failed to provide adequate warnings to the medical community and patients, and continued to promote long term use of Reglan/Metoclopramide as safe and effective.

169. The defective warnings and labeling on Reglan/Metoclopramide was the substantial factor in bringing about the injuries to the Plaintiff.

170. As the direct and proximate cause of the defective condition of Reglan/Metoclopramide as manufactured and/or supplied by Defendants, and specifically their failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XI: NEGLIGENCE
PLIVA

171. Plaintiff incorporates by reference all of the above paragraphs.

172. Defendant, Pliva is a generic pharmaceutical manufacturer who is in the business of researching, manufacturing and distributing generic pharmaceuticals, including Reglan/metoclopramide. Pliva is a wholly owned subsidiary of Barr Pharmaceuticals, Inc., which has recently been acquired by Teva.

173. By way of information and belief Plaintiff ingested Reglan/metoclopramide that was manufactured and sold by the Defendant during the time period in question.

174. Under the ANDA process, the Code of Federal Regulations required Defendant, Pliva to submit labels for Reglan/metoclopramide initially identical in all material aspects to the reference listed drug label.

175. Under the Code of Federal Regulations, Pliva had a duty to ensure its Reglan/ metoclopramide warnings to the medical community were accurate and adequate, and to conduct post market safety surveillance, to review all adverse drug event information (ADE) and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/metoclopramide.

176. Under the Code of Federal Regulations if a generic drug manufacturer, such as Pliva, discovers subsequent information in the course of the fulfillment of their duties as outlined above, they are obligated to report that information to the medical community, and thereby Plaintiff's physician, so

that the Plaintiff and other foreseeable users of Reglan/metoclopramide are apprised of warnings and updates that are accurate and adequate.

177. Despite these requirements, Defendant failed to investigate the accuracy of its generic bioequivalent metoclopramide and/or metoclopramide HCL drug label. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

178. Based upon information and belief Defendant unreasonably failed to review the medical literature for its Reglan/metoclopramide and instead relied upon the name brand manufacturer and the RLD to review the aforementioned medical literature and thus failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Reglan/metoclopramide. As a result Plaintiff came to rely upon the safety and soundness of said drug, and so failed to appreciate or have knowledge of the risk associated with long-term ingestion of the drug.

179. Defendant was negligent and breached duties owed to Plaintiff as a user and consumer with respect to its manufacture and sale of Reglan/metoclopramide, as set forth otherwise herein and for reasons including, but not limited to the following:

a) Failing to reasonably disseminate to physicians, through package inserts, the publication of the Physician's Desk Reference (PDR), and otherwise, information concerning the properties and effects of Reglan/metoclopramide, with the intention that physicians would rely upon that information in their decisions concerning the prescribing of drug therapy for their patients;

b) Failing to reasonably accompany the drug with adequate warnings, instructions and updates regarding the adverse and permanent side effects including death (particularly with foreseeable long term use), despite Defendant's knowledge of the defects and risks associated with Reglan/metoclopramide ingestion;

c) Failing to reasonably and accurately represent to the prescribing physician(s),and ultimately thereby the users and consumers that the drug can cause central nervous

system side effects and significant and permanent extrapyramidal symptoms, particularly with foreseeable long term use;

d) Failing to conduct adequate and reasonable testing on the risks and side effects associated with long term ingestion of Reglan/metoclopramide and conduct post-marketing surveillance to determine the safety of Reglan/metoclopramide and failing to monitor all relevant scientific literature related to Reglan/metoclopramide;

e) Failing to adequately and reasonably inform the medical community that Reglan/metoclopramide was unreasonably dangerous for long-term use, despite having knowledge, through their own studies and studies by independent investigators, that physicians frequently prescribed Reglan/metoclopramide for long-term use;

f) Failing to reasonably and sufficiently disclose information in package inserts for Reglan/metoclopramide or through the PDR, the risks of Tardive Dyskinesia and other extrapyramidal side effects of Reglan/metoclopramide, including, but not limited to the increased risks for patients who receive the drug for 12 weeks or longer;

g) Failing to reasonably and promptly correct and/or amend the package inserts, PDR monographs, and literature regarding the risks of long term ingestion of Reglan/metoclopramide, once the side effects became actually or constructively known; with the knowledge that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients;

h) Failing to reasonably and properly conduct adequate post-marketing surveillance and testing to determine the safety of the product, particularly with foreseeable long-term use, despite Defendant's knowledge of the defects and risks associated with Reglan/metoclopramide ingestion;

i) Failing to reasonably and adequately warn that the long term use of Reglan/metoclopramide may result in side effects such as Depression with Suicidal Ideation, Akathisia, Akinesia, Tardive Dyskinesia, Tardive Dystonia, Visual Disturbances, etc., and that these side effects were permanent in nature;

j) Willfully and deliberately failing to adequately disclose all actual and/or constructively known risks regarding Reglan/metoclopramide and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare.

180. The negligence described above directly and proximately caused Plaintiff's severe and permanent injuries, in that it or they directly and in natural and continuous sequence produced and contributed substantially thereto, including but not limited to the fact that Plaintiff's prescribing

physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

181. The Defendant breached its duties, and proximately caused through a defective product and/or through its acts of negligence, severe and permanent damage to Plaintiff.

182. Defendant is therefore liable for intentional, reckless, and/or negligent omission, concealment and failure to warn of the design and manufacturing defects which caused Plaintiff to suffer injury, harm and economic loss, including medical bills, medical expenses, including a permanent and substantial physical disability.

183. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XII: BREACH OF WARRANTY
PLIVA

184. Plaintiff incorporates by reference all of the above paragraphs.

185. Through its promotional statement(s) and product literature Defendant expressly warranted to the medical community and thereby ultimately the user/consumer (Plaintiff) that Reglan/metoclopramide was safe and capable of treating gastrointestinal disorders over an extended period of time (i.e. over 12 weeks), despite Defendant's knowledge to the contrary. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not

have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

186. Defendant knew that its warranties regarding safety for long-term use would be relied upon by the medical community which included ordinary, reasonable and prudent physicians who would share that information with others in the medical community and that eventually prescribing physicians and the public (including Plaintiff) would come to rely and did rely upon Defendant's express warranties about Reglan/metoclopramide's safety for long-term use.

187. Defendant's warranties about the safety of Reglan/metoclopramide for long-term use were false and intentionally misleading.

188. Despite knowledge to the contrary Defendant continued to promote, sell and market the safety of Reglan/metoclopramide, while having knowledge of the design, manufacturing, safety defects and risk that it posed to the user/consumer of developing severe neurological side effects such as Tardive Dyskinesia with prolonged use of the drug.

164. Defendant through its marketing, promoting, selling and distribution of Reglan/metoclopramide represented that its drug product was of merchantable quality and safe and fit for its intended use of treating gastrointestinal symptoms such as gastroesophageal reflux and gastroparesis. At the same time Defendant continued to conceal and fail to warn of the risks and side effects of neurological disorders such as Tardive Dyskinesia and Akathisia which were associated with long-term use of Reglan/metoclopramide and continued to impliedly warrant the medical soundness of the drug product to the medical community and thereby general public.

189. Plaintiff and her prescribing physician(s) reasonably relied on the presumption that the Defendant would provide notice, disclosure or warnings of any risks associated with Reglan/metoclopramide's merchantability, quality, safety and fitness for its intended use.

190. Contrary to such implied warranties, Reglan/metoclopramide was not of merchantable quality or safe or fit for its intended use, because the drugs were and are unreasonably dangerous and unfit for the ordinary, intended and foreseeable use due to the adverse side effects.

191. As a direct and proximate result of the Defendant's breach of warranty, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

192. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff suffered among other things extreme emotional distress, anguish, physical and mental suffering, weakness and involuntary shaking, tremors and continuous involuntary movements of her body rendering her physically and permanently disabled.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XIII: MISREPRESENTATION AND FRAUD
PLIVA

193. Plaintiff incorporates by reference all of the above paragraphs.

194. Defendant intentionally and negligently disseminated misleading information to physicians across the country, through the PDR, about the risks of long-term ingestion of Reglan/metoclopramide and the increased risk of extrapyramidal side effects, including tardive dyskinesia. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

195. Defendant misrepresented the soundness and reliability of Reglan/metoclopramide to physicians and the medical community and thereby ultimately the general public through promotional and marketing campaigns. It misrepresented that the drug was safe and effective when used as prescribed , when in fact, it was dangerous to the health of patients. Defendant continued these misrepresentations for an extended period of time, without disclosing material information that was available to them.

196. Defendant concealed the design, manufacturing and safety defects from the public by withholding information pertaining to the design, manufacturing, safety defects and risks of severe and permanent neurological side effects related to the ingestion and long-term use of Reglan/metoclopramide, while knowingly presenting to the medical community and thereby ultimately the general public that the drug was sound and reliable.

197. Defendant knew or should have known of the risks that Reglan/metoclopramide presented to users/consumers when they unknowingly ingested the drug product as prescribed.

198. Defendant failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of Reglan/metoclopramide and otherwise failed to exercise reasonable care in transmitting information to the medical community and thereby ultimately to the general public, users/consumers, including Plaintiff.

199. Defendant made these representations concerning Reglan/metoclopramide in the course of its business as designer, manufacturer and distributor of the drug.

200. Such representations were made by the Defendant with the intent to defraud and/or deceive the medical community and thereby ultimately the user/consumer of Reglan/metoclopramide and with the knowledge and intent to induce reliance upon these representations and use of said drug product.

201. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

202. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff suffered among other things extreme emotional distress, anguish, physical and mental suffering, weakness and involuntary shaking, tremors and continuous involuntary movements of her body rendering her physically and permanently disabled.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XIV: STRICT LIABILITY
PLIVA

203. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

204. Plaintiff is in the class of persons that Defendant Pliva USA, Inc. should reasonably foresee as being subject to the harm caused by defectively designed pharmaceuticals, including the Reglan/Metoclopramide at issue in this lawsuit, insofar as Plaintiff Shirley Gross was the type of person for whom the Reglan/Metoclopramide was intended to be used.

205. Defendant Pliva USA, Inc., which is engaged in the business of selling the products, manufactured and supplied pharmaceuticals, including the Reglan/Metoclopramide at issue in this lawsuit, and placed it into the stream of commerce in a defective and unreasonably dangerous condition

such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

206. The Reglan/Metoclopramide supplied to Plaintiff was defective in design and formulation and unreasonably dangerous when it left the hands of Defendant, the manufacturers and suppliers, and they reached the user and consumer of the products, Plaintiff, without substantial alteration in the condition in which they were sold.

207. The Reglan/Metoclopramide manufactured by the Defendant was unreasonable and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding these products.

208. Defendant Pliva USA, Inc.'s Reglan/Metoclopramide was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results of such studies.

209. Defendant Pliva USA, Inc.'s Reglan/Metoclopramide was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their Reglan/Metoclopramide, they failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

210. The product defects alleged above were a substantial contributing cause of the injuries suffered by Plaintiff. Specifically, Reglan/Metoclopramide caused Plaintiff to suffer permanent and disabling injuries, specifically Tardive Dyskinesia. Plaintiff will also require future medical care. In addition, Plaintiff has suffered mental distress and anguish and has suffered permanent impairment.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XV: STRICT PRODUCTS LIABILITY: FAILURE TO WARN
PLIVA

211. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

212. Defendant Pliva USA, Inc. manufactured Reglan/Metoclopramide and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

213. Defendant Pliva USA, Inc.'s Reglan/Metoclopramide was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results.

214. Defendant Pliva USA, Inc.'s Reglan/Metoclopramide was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their Reglan/Metoclopramide, they failed to provide adequate warnings to the medical community and patients, and continued to promote long term use of Reglan/Metoclopramide as safe and effective.

215. The defective warnings and labeling on Reglan/Metoclopramide was the substantial factor in bringing about the injuries to the Plaintiff.

216. As the direct and proximate cause of the defective condition of Reglan/Metoclopramide as manufactured and/or supplied by Defendants, and specifically their failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XVI: NEGLIGENCE
TEVA

217. Plaintiff incorporates by reference all of the above paragraphs.

218. Defendant, Teva specializes in the development, manufacture and sale of generic pharmaceuticals, including Reglan/metoclopramide.

219. Defendant, Teva, has facilities in Maryland and during all times material hereto regularly conducted business and supplied pharmaceutical medications, including but not limited to generic Reglan/metoclopramide.

220. By way of information and belief Plaintiff ingested Reglan/metoclopramide that was manufactured and sold by the Defendant during the time period in question.

221. Based upon information and belief Defendant, Teva submitted an Abbreviated New Drug Application (ANDA) to the FDA, based on representations made by the RLD companies, requesting permission to manufacture, market and distribute generic Reglan/metoclopramide.

222. Under the ANDA process, the Code of Federal Regulations required Defendant, Teva to submit labels for Reglan/metoclopramide initially identical in all material aspects to the reference listed drug label.

223. Under the Code of Federal Regulations, Teva had a duty to ensure its Reglan/ metoclopramide warnings to the medical community were accurate and adequate, and to conduct post market safety surveillance, to review all adverse drug event information (ADE) and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/metoclopramide.

224. Under the Code of Federal Regulations if a generic drug manufacturer such as Teva discovers subsequent information in the course of the fulfillment of their duties as outlined above, they are obligated to report that information to the medical community, and thereby Plaintiff's physician, so that the Plaintiff and other foreseeable users of Reglan/metoclopramide are apprised of warnings and updates that are accurate and adequate.

225. Despite these requirements, Defendant, Teva failed to investigate the accuracy of its generic bioequivalent metoclopramide and/or metoclopramide HCL drug label. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

226. Based upon information and belief Defendant, Teva unreasonably failed to review the medical literature for its Reglan/metoclopramide and instead relied upon the name brand manufacturer and the RLD to review the aforementioned medical literature and thus failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Reglan/metoclopramide. As a result, Plaintiff came to rely upon the safety and soundness of said drug, and so failed to appreciate or have knowledge of the risk associated with long-term ingestion of the drug.

227. Defendant, Teva was negligent and breached duties owed to the Plaintiff as user and consumer with respect to its manufacture and sale of Reglan/metoclopramide, as set forth otherwise herein and for reasons including, but not limited to the following:

a) Failing to reasonably disseminate to physicians, through package inserts, the publication of the Physician's Desk Reference (PDR), and otherwise, information concerning the properties and effects of Reglan/metoclopramide, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients;

b) Failing to reasonably accompany the drug with adequate warnings, instructions and updates regarding the adverse and permanent side effects including death (particularly with foreseeable long term use), despite Defendant's knowledge of the defects and risks associated with Reglan/metoclopramide ingestion;

c) Failing to reasonably and accurately represent to the prescribing physician(s),and ultimately thereby users and consumers that the drug that can cause central nervous system side effects and significant and permanent extrapyramidal symptoms, particularly with foreseeable long term use;

d) Failing to conduct adequate and reasonable testing on the risks and side effects associated with long term ingestion of Reglan/metoclopramide and conduct post-marketing surveillance to determine the safety of Reglan/metoclopramide and failing to monitor all relevant scientific literature related to Reglan/metoclopramide;

e) Failing to adequately and reasonably inform the medical community that Reglan/metoclopramide was unreasonably dangerous for long-term use, despite having knowledge, through studies, that physicians frequently prescribed Reglan/metoclopramide for long-term use;

f) Failing to reasonably and sufficiently disclose information in package inserts for Reglan/metoclopramide or through the PDR, the risks of Tardive Dyskinesia and other extrapyramidal side effects of Reglan/metoclopramide, including, but not limited to the increased risks for patients who receive the drug for 12 weeks or longer;

g) Failing to reasonably and promptly correct and/or amend the package inserts, PDR monographs, and literature regarding the risks of long term ingestion of Reglan/metoclopramide, once the side effects became actually or constructively known; with the knowledge that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients;

h) Failing to reasonably and properly conduct adequate post-marketing surveillance and testing to determine the safety of the product, particularly with foreseeable long-term use, despite Defendant's knowledge of the defects and risks associated with Reglan/metoclopramide ingestion;

i) Failing to reasonably and adequately warn that the long term use of Reglan/metoclopramide may result in side effects such as Depression with Suicidal Ideation, Akathisia, Akinesia, Tardive Dyskinesia, Tardive Dystonia, Visual Disturbances, etc., and that these side effects were permanent in nature;

j) Willfully and deliberately failing to adequately disclose all actual and/or constructively known risks regarding Reglan/metoclopramide and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare.

228. The negligence described above directly and proximately caused Plaintiff's severe and permanent injuries, including but not limited to the fact that Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

229. The Defendant breached its duties, and proximately caused through a defective product and/or through its acts of negligence, severe and permanent damage.

230. Defendant, Teva is therefore liable for intentional, reckless, and/or negligent omission, concealment and failure to warn of the design and manufacturing defects which caused Plaintiff to suffer injury, harm and economic loss, including medical bills, medical expenses, including a permanent and substantial physical disability.

231. As a direct and proximate result of the acts and omissions of the Defendant, ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XVII: BREACH OF WARRANTY
TEVA

232. Plaintiff incorporates by reference all of the above paragraphs.

233. Through its promotional statement(s)and product literature Defendant expressly warranted to the medical community and thereby ultimately the user/consumer (Plaintiff) that

Reglan/metoclopramide was safe and capable of treating disorders over an extended period of time (i.e. over 12 weeks), despite Defendant's knowledge to the contrary.

234. Defendant knew that its warranties regarding safety for long-term use would be relied upon by the medical community which included ordinary, reasonable and prudent physicians who would share that information with others in the medical community and that eventually prescribing physicians and the public (including Plaintiff) would come to rely and did rely upon Defendant's express warranties about Reglan/metoclopramide's safety for long-term use.

235. Defendant's express warranties about the safety of Reglan/metoclopramide for long-term use were false and intentionally misleading.

236. Despite knowledge to the contrary Defendant continued to promote, sell and market the safety of Reglan/metoclopramide, while having knowledge of the design, manufacturing, safety defects and risk that it posed to the user/consumer of developing severe neurological side effects such as Tardive Dyskinesia with prolonged use of the drug.

237. Defendant through its marketing, promoting, selling and distribution of Reglan/metoclopramide represented that its drug product was of merchantable quality and safe and fit for its intended use of treating gastrointestinal symptoms such as gastroesophageal reflux and gastroparesis. At the same time Defendant continued to conceal and fail to warn of the risks and side effects of neurological disorders such as Tardive Dyskinesia and Akathisia which were associated with long-term use of Reglan/metoclopramide and continued to impliedly warrant the medical soundness of the drug product to the medical community and thereby general public. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

238. Plaintiff and her prescribing physician(s) reasonably relied on the presumption that the Defendant would provide notice, disclosure or warnings of any risks associated with Reglan/metoclopramide's merchantability, quality, safety and fitness for its intended use.

239. Contrary to such implied warranties, Reglan/metoclopramide was not of merchantable quality or safe or fit for its intended use, because the drugs were and are unreasonably dangerous and unfit for the ordinary, intended and foreseeable use due to the adverse side effects.

240. As a direct and proximate result of the Defendant's breach of warranty, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XVIII: MISREPRESENTATION AND FRAUD
TEVA

241. Plaintiff incorporates by reference all of the above paragraphs.

242. Defendant intentionally and negligently disseminated misleading information to physicians across the country, through the PDR, about the risks of long-term ingestion of Reglan/metoclopramide and the increased risk of extrapyramidal side effects, including tardive dyskinesia.

243. Defendant misrepresented the soundness and reliability of Reglan/metoclopramide to physicians and the medical community and thereby ultimately the general public through promotional and marketing campaigns. It misrepresented that the drug was safe and effective when used as

prescribed , when in fact, it was dangerous to the health of patients. Defendant continued these misrepresentations for an extended period of time, without disclosing material information that was available to them. As a direct result, Plaintiff's prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had the physician(s) known of the significant risks of, inter alia, Tardive Dyskinesia and Akathisia.

244. Defendant concealed the design, manufacturing and safety defects from the public by withholding information pertaining to the design, manufacturing, safety defects and risks of severe and permanent neurological side effects related to the ingestion and long-term use of Reglan/metoclopramide, while knowingly presenting to the medical community and thereby ultimately the general public that the drug was sound and reliable.

245. Defendant knew of the risks that Reglan/metoclopramide presented to users/consumers when they unknowingly ingested the drug product as prescribed for periods exceeding 12 weeks in duration.

246. Defendant failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of Reglan/metoclopramide and otherwise failed to exercise reasonable care in transmitting information to the medical community and thereby ultimately to the general public, users/consumers, including Plaintiff.

247. Defendant made these representations concerning Reglan/metoclopramide in the course of its business as designer, manufacturer and distributor of the drug.

248. Such representations were made by the Defendant with the intent to defraud and/or deceive the medical community and thereby ultimately the user/consumer of Reglan/metoclopramide and with the knowledge and intent to induce reliance upon these representations and use of said drug product.

249. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff ingested Reglan/metoclopramide as prescribed and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder known as Tardive Dyskinesia and Akathisia.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XIX: STRICT LIABILITY
TEVA

250. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

251. Plaintiff is in the class of persons that Defendant Teva Pharmaceuticals USA, Inc. should reasonably foresee as being subject to the harm caused by defectively designed pharmaceuticals, including the Reglan/Metoclopramide at issue in this lawsuit, insofar as Plaintiff Shirley Gross was the type of person for whom the Reglan/Metoclopramide was intended to be used.

252. Defendant Teva Pharmaceuticals USA, Inc. is engaged in the business of selling the products, manufactured and supplied pharmaceuticals, including the Reglan/Metoclopramide at issue in this lawsuit, and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

253. The Reglan/Metoclopramide supplied to Plaintiff was defective in design and formulation and unreasonably dangerous when it left the hands of Defendant, the manufacturers and suppliers, and

they reached the user and consumer of the products, Plaintiff, without substantial alteration in the condition in which they were sold.

254. The Reglan/Metoclopramide manufactured by the Defendant was unreasonable and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding these products.

255. Defendant Teva Pharmaceuticals USA, Inc.'s Reglan/Metoclopramide was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results of such studies.

256. Defendant Teva Pharmaceuticals USA, Inc.'s Reglan/Metoclopramide was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their Reglan/Metoclopramide, they failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

257. The product defects alleged above were a substantial contributing cause of the injuries suffered by Plaintiff. Specifically, Reglan/Metoclopramide caused Plaintiff to suffer permanent and disabling injuries, specifically Tardive Dyskinesia. Plaintiff will also require future medical care. In addition, Plaintiff has suffered mental distress and anguish and has suffered permanent impairment.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XX: STRICT PRODUCTS LIABILITY: FAILURE TO WARN TEVA

258. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

259. Defendant Teva Pharmaceuticals USA, Inc. manufactured Reglan/Metoclopramide and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

260. Defendant Teva Pharmaceuticals USA, Inc.'s Reglan/Metoclopramide was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results.

261. Defendant Teva Pharmaceuticals USA, Inc.'s Reglan/Metoclopramide was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their Reglan/Metoclopramide, they failed to provide adequate warnings to the medical community and patients, and continued to promote long term use of Reglan/Metoclopramide as safe and effective.

262. The defective warnings and labeling on Reglan/Metoclopramide was the substantial factor in bringing about the injuries to the Plaintiff.

263. As the direct and proximate cause of the defective condition of Reglan/Metoclopramide as manufactured and/or supplied by Defendants, and specifically their failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

DAMAGES

264. Plaintiff incorporates by reference all of the above paragraphs.

265. As a producing and proximate result of the above-describing acts and omissions of Defendants Pfizer, Wyeth, Schwarz, Pliva, and Teva, Plaintiff has incurred actual damages in excess of $75,000.00:

(1) Reasonable and necessary medical expenses incurred in the past;

(2) Reasonable and necessary medical expenses reasonably likely to be incurred in the future;

(3) Conscious physical pain and suffering experienced in the past;

(4) Conscious physical pain and suffering reasonably likely to be experienced in the future;

(5) Mental anguish in the past;

(6) Mental anguish likely to be experienced in the future;

(7) Physical disfigurement in the past;

(8) Physical disfigurement likely to be experienced in the future;

(9) Physical impairment in the past;

(10) Physical impairment likely to be experienced in the future;

(11) Pre and post-judgment interest at the lawful rate;

(12) Exemplary damages;

(13) Attorneys' fees, costs and treble damages;

(14) Such other applicable damages as the Court deems appropriate.

266. At all times relevant hereto, the Defendants' acts or omissions as set forth in Counts I to XX, and as set forth herein, were done with conscious indifference and reckless disregard for the safety

and well being of the users of Reglan/metoclopramide, including Plaintiff in particular and such conduct justifies the imposition of punitive damages against the Defendants both individually and collectively.

267. The Defendants developed, manufactured, tested, packaged, marketed, sold and/or distributed Reglan/metoclopramide to the general public despite knowledge that the design, manufacturing and/or side effect defects associated with the drug unreasonably caused or had the potential to unreasonably cause injuries with the foreseeable/ prescribed use of the drug when used for durations exceeding 12 weeks.

268. Based upon information and belief, Defendants' had prior knowledge and information within their possession that indicated Reglan/metoclopramide was defective and unreasonably dangerous, including the fact that it was capable of causing severe physical, mental and emotional injuries to those who ingested the drug for longer than 12 weeks and deliberately and with conscious disregard failed to warn prescribing physicians, particularly Plaintiff's prescribing physician(s) of this danger.

269. The Defendants' misrepresentations and omissions regarding the safety and side effects of Reglan/metoclopramide, were made willfully, wantonly, recklessly and in conscious disregard of the user of said drug product.

270. Due to Defendants' willful, wanton, reckless and outrageous conduct, Plaintiff and her prescribing physician(s) were unreasonably deprived of any meaningful opportunity in measuring the level of risk with regard to ingestion of Reglan/metoclopramide and Plaintiff prescribing physician(s) prescribed Reglan/metoclopramide in a manner that they would not have, had they known and been reasonably informed of the dangers.

271. Defendants, willfully, unreasonably and with conscious disregard failed to disclose material safety information regarding the serious and permanent side effects caused by ingesting Reglan/metoclopramide for periods exceeding 12 weeks duration.

272. Defendants, as a result of their participation as defendants in previous litigation concerning Reglan/metoclopramide products received clear notice of suppression of important safety information concerning Reglan/metoclopramide, yet despite this notice consciously chose to ignore the information and joined consciously in the suppression of said information.

273. The actions of the Defendants, as set forth all preceding paragraphs constitutes willful and wanton misconduct in conscious disregard of the rights and safety of the Plaintiff and thereby warrants the imposition of punitive damages against each Defendant.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory damages, for punitive damages in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right. The sum sued upon is in excess of the amount requiring submission at arbitration.

DATE: January 15, 2010.

Respectfully submitted,

/s/ Robert K. Jenner
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ATTORNEYS FOR PLAINTIFFS

JURY DEMAND

Plaintiff demands a jury trial on all issues to triable.

/s/ Robert K. Jenner_____
ROBERT K. JENNER